DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

February 20, 2015

Volcano Corporation
Neeta Sharma
Director, Regulatory Affairs
3721 Valley Centre Drive, Suite 500
San Diego, CA 92130

Re: K143122
Trade/Device Name: Volcano Harvest iFR Modality
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic Pulsed Echo Imaging System
Regulatory Class: Class II
Product Code: IYO
Dated: January 20, 2015
Received: January 22, 2015

Dear Ms. Sharma,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Melissa A. Torres -S

For Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

5l0(k) Number (if known) K143122

Device Name Volcano Harvest iFR® Modality

Indications for Use

The Volcano iFR® Harvest Modality is an offline analysis tool of the currently marketed vasodilator-free pressure measurement module, iFR® Modality of the Volcano s5/s5i/CORE and CORE Mobile systems. It is intended to calculate iFR values from hyperemia-free FFR pressure recordings in a laptop or desktop setting only.

Prescription Use ___X____ OR Over the Counter Use _____
(Per 21 CFR 801.109)

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

510 (k) SUMMARY

SPONSOR:	Volcano Corporation 3721 Valley Center Drive San Diego, CA 92130
CONTACT/SUBMITTER:	Neeta Sharma Director, Regulatory Affairs Volcano Corporation 3721 Valley Center Drive San Diego, CA 92130 Tel: (858) 720-4187 Fax :(858) 720-0335
DATE PREPARED:	February 18, 2015
DEVICE:	Volcano Harvest iFR® Modality
TRADE NAME:	Volcano Harvest iFR® Modality
COMMON NAME:	Ultrasonic Pulsed Echo Imaging System
CLASSIFICATION:	21 CFR Part 892.1560 IYO: System, Imaging, Pulsed Echo, Ultrasonic Class II Device
PREDICATE DEVICE:	Volcano iFR Modality (K133323)
DEVICE DESCRIPTION:	The Volcano Harvest iFR® Modality is a software tool designed to calculate offline iFR values from hyperemia-free FFR pressure recordings made using Volcano's s5 v3.2.x software. It takes an existing FFR case file, separates the baseline (iFR) and Pd/Pa (FFR under resting conditions) pressure runs, calculates the iFR values from the baseline runs, and prepares a report summarizing the values. Input case files are collected and archived on the s5 or s5i console from Volcano Corporation.
INTENDED USE:	The Volcano iFR® Harvest Modality is an offline analysis tool of the currently marketed vasodilator-free pressure measurement module, iFR® Modality of the Volcano s5/s5i/CORE and CORE Mobile systems. It is intended to calculate iFR values from hyperemia-free FFR pressure recordings in a laptop or desktop setting only.

COMPARISON OF CHARACTERISTICS:

The Harvest iFR® Modality is an offline version of the iFR Modality with similar in intended use that both software are designed to measure blood pressure in the coronary and peripheral vasculature. Both softwares have identical technological features. The Harvest iFR® Modality software allows for an offline analysis of the pressure measurement readings to be done if desired by the physician in a laptop or desktop setting.

PERFORMANCE DATA:

Performance testing completed for a determination of substantial equivalence included the following:

- Software Verification
- Software Validation

The results of the performance data demonstrate equivalence to the predicate device.